

**MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS  
RADIATION SAFETY SECTION  
IONIZING RADIATION RULES GOVERNING THE USE OF RADIATION  
MACHINES**

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## PART 1. GENERAL PROVISIONS FOR THE USE OF RADIATION MACHINES

### R 333.5001 Scope.

**Rule 1. (1)** Except as otherwise specified, these rules apply to a person who acquires, receives, owns, possesses, uses, stores, or transfers a radiation machine.

**(2)** Terms used in these rules shall have the same meaning as defined in the act.

History: 2016 MR 10, Eff. May 25, 2016

### R 333.5002 Definitions; A.

**Rule 2. (1)** "Absorbed dose" means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the gray (Gy) and the rad.

**(2)** "Accelerator" means a machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt (MeV).

**(3)** "Act" means 1978 PA 368, MCL 333.1101 to 333.25211. The terms defined in the act have the same meanings when used in these rules.

**(4)** "Annual" means a period of 12 consecutive months.

**(5)** "As low as reasonably achievable" (ALARA) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these rules as is practical, consistent with the purpose for which the registered activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of registered radiation machines in the public interest.

History: 2016 MR 10, Eff. May 25, 2016

### R 333.5003 Definitions; C.

**Rule 3. (1)** "Calendar quarter" means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than 1 calendar quarter and no day in any 1 year is omitted from inclusion within a calendar quarter. The method observed by the registrant for determining calendar quarters shall only be changed at the beginning of a year.

**(2)** "Calibration" means the determination of either of the following:

- (a)** The response or reading of an instrument relative to a series of known radiation values

over the range of the instrument.

- (b)** The strength of a source of radiation relative to a standard.

**(3)** "Collective dose" means the sum of the individual doses received in a given period of time by a specified population from exposure to a specified source of radiation.

**(4)** "Controlled area" means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the registrant for any reason.

History: 2016 MR 10, Eff. May 25, 2016

### R 333.5004 Definitions; D.

**Rule 4. (1)** "Deep dose equivalent" ( $H_d$ ), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter ( $1000 \text{ mg/cm}^2$ ).

**(2)** "Department" means the department of licensing and regulatory affairs.

**(3)** "Dose" or "radiation dose" means absorbed dose, dose equivalent, or effective dose equivalent as appropriate.

**(4)** "Dose equivalent ( $H_T$ )" means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the sievert (Sv) and rem.

**(5)** "Dose limits" or "limits" means the permissible upper bounds of radiation doses established under these rules.

History: 2016 MR 10, Eff. May 25, 2016

### R 333.5005 Definitions; E.

**Rule 5. (1)** "Effective dose equivalent ( $H_E$ )" means the sum of the products of the dose equivalent to the organ or tissue ( $H_T$ ) and the weighting factor ( $W_T$ ) applicable to each of the body organs or tissues that are irradiated ( $H_E = \sum W_T H_T$ ).

**(2)** "Embryo or fetus" means the developing human organism from conception until the time of birth.

**(3)** "Entrance or access point" means a location through which an individual could gain access to radiation areas. This includes entry or exit portals of sufficient size to permit human entry, irrespective of their intended use.

**(4)** "Exposure" means being exposed to ionizing radiation.

**(5)** "External dose" means that portion of the dose equivalent received from a source of radiation outside the body.

(6) "Extremity" means hand, elbow, and arm below the elbow, foot, knee, and leg below the knee.

(7) "Extremity radiography" means radiography of the hand or arm excluding the shaft of the humerus or the foot or leg excluding the shaft of the femur.

History: 2016 MR 10, Eff. May 25, 2016

#### **R 333.5006 Definitions; H.**

**Rule 6. (1)** "High radiation area" means an area, accessible to individuals, in which radiation levels from radiation sources external to the body could result in an individual receiving a dose equivalent in excess of 1 mSv (0.1 rem) in 1 hour at 30 centimeters from a source of radiation or 30 centimeters from any surface that the radiation penetrates.

(2) "Human use" means the internal or external administration of radiation to human beings.

History: 2016 MR 10, Eff. May 25, 2016

#### **R 333.5007 Definitions; I.**

**Rule 7. (1)** "Individual" means a human being.

(2) "Individual monitoring" means the assessment of dose equivalent by the use of individual monitoring devices or by the use of survey data.

(3) "Individual monitoring device" means a device designed to be worn by a single individual for the assessment of dose equivalent. Film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and optically stimulated luminescence (OSL) dosimeters are examples of individual monitoring devices.

(4) "Inspection" means an official examination or observation including, but not limited to, tests, surveys, and monitoring to determine compliance with the act, these rules, registration conditions or orders of the department.

(5) "Interlock" means a device arranged or connected such that the occurrence of an event or condition is required before a second event or condition can occur or continue to occur.

History: 2016 MR 10, Eff. May 25, 2016

#### **R 333.5008 Definitions; L to O.**

**Rule 8. (1)** "Lens dose equivalent (LDE)" means the external exposure to the lens of the eye as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm<sup>2</sup>).

(2) "Member of the public" means an individual except when that individual is receiving an occupational dose.

(3) "Occupational dose" means the dose received by an individual in the course of employment in which the individual's assigned duties for the registrant involve exposure to sources of radiation, whether in the possession of the registrant or other person.

History: 2016 MR 10, Eff. May 25, 2016

#### **R 333.5009 Definitions; P and Q.**

**Rule 9. (1)** "Physician" means an individual licensed under section 17011 or 17511 of article 15 of the public health code, 1978 PA 306, MCL 333.17011 and 333.17511 to practice medicine or osteopathic medicine.

(2) "Protective apron" means an apron made of radiation-attenuating materials used to reduce exposure to radiation.

(3) "Public dose" means the dose received by a member of the public from exposure to a radiation machine under the control of the registrant. Public dose does not include occupational dose, or doses received from a medical administration the individual has received, or from voluntary participation in medical research programs.

(4) "Quality factor" (Q) means the modifying factor, listed in tables 20-1 and 20-2, that is used to derive dose equivalent from absorbed dose.

History: 2016 MR 10, Eff. May 25, 2016

#### **R 333.5010 Definitions; R.**

**Rule 10. (1)** "Radiation" means ionizing radiation. Radiation, as used in these rules, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

(2) "Radiation area" means an area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (5 mrem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

(3) "Radiation machine" means a machine that emits ionizing radiation when energized.

(4) "Radiation protection supervisor" means the individual specified by the registrant who has the knowledge, authority, and responsibility for radiation protection.

(5) "Registrant" means a person who is registered with the department and is legally obligated to register with the department pursuant to these rules and the act.

(6) "Registration" for the purpose of these rules means registration of a radiation machine in writing with the department.

(7) "Research and development" means 1 of the following:

- (a) Theoretical analysis, exploration, or experimentation.
- (b) The extension of investigative findings and theories of a scientific or technical nature into practical application for experimental and demonstration purposes, including the experimental production and testing of models, devices, equipment, materials, and processes. Research and development does not include the internal or external administration of radiation to human beings.

(8) "Restricted area" means an area, access to which is limited by the registrant, for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

(9) "Roentgen" means the special unit of exposure. One roentgen (R) equals  $2.58 \times 10^{-4}$  coulombs per kilogram of air.

History: 2016 MR 10, Eff. May 25, 2016

### R 333.5011 Definitions; S.

**Rule 11. (1)** "Shallow dose equivalent" ( $H_s$ ), which applies to the external exposure of the skin or an extremity, means the dose equivalent at a tissue depth of 0.007 centimeter ( $7 \text{ mg/cm}^2$ ) averaged over an area of 1 square centimeter.

(2) "SI" means the abbreviation for the international system of units.

(3) "Stochastic effect" means a health effect that occurs randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

(4) "Survey" means an evaluation of the radiological conditions and potential hazards incident to the use of radiation machines. When appropriate, this evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation.

History: 2016 MR 10, Eff. May 25, 2016

### R 333.5012 Definitions; T to V.

**Rule 12. (1)** "Traceable to a national standard" means an instrument is calibrated at either the national institute of standards and technology (NIST) or at a calibration laboratory that participates in a proficiency program with the NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within 3% of the national standard in the appropriate energy range.

(2) "Unrestricted area" or "uncontrolled area" means an area, access to which is neither limited nor controlled by the registrant for purposes of protection of individuals from exposure to radiation, or an area used for residential quarters.

(3) "Very high radiation area" means an area, accessible to individuals, in which radiation levels from a radiation machine could result in an individual receiving an absorbed dose in excess of 5 Gy (500 rads) in 1 hour at 1 meter from a radiation machine or 1 meter from any surface that the radiation penetrates.

History: 2016 MR 10, Eff. May 25, 2016

### R 333.5013 Definitions; W to Y.

**Rule 13. (1)** "Week" means 7 consecutive days starting on Sunday.

(2) "Weighting factor"  $w_T$  for an organ or tissue (T) means the proportion of the risk of stochastic effects resulting from irradiation of that organ or tissue to the total risk of stochastic effects when the whole body is irradiated uniformly. For calculating the effective dose equivalent, the values of  $w_T$  are as follows:

#### ORGAN DOSE WEIGHTING FACTORS

Organ or Tissue	$w_T$
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30
Whole Body	1.00

(3) "Whole body" means, for purposes of external exposure, head, trunk including male gonads, arms above the elbow, or legs above the knee.

(4) "Worker" means an individual engaged in activities under a registration issued by the department and controlled by a registrant, but does not include the registrant.

(5) "Year" means the period of time beginning in January used to determine compliance with the provisions of these rules. The registrant may change the starting date of the year used to determine compliance by the registrant if the change is made at the beginning of the year. If a registrant changes in a year, the registrant shall assure that no day is omitted or duplicated in consecutive years.

History: 2016 MR 10, Eff. May 25, 2016

## EXEMPTIONS

### R 333.5015 Exemptions.

**Rule 15.** The department may, in response to a request or on its own initiative, grant an exemption or exception from the requirements of these rules as it determines is authorized by law and shall not result in an undue hazard to public health and safety, property, or the environment.

History: 2016 MR 10, Eff. May 25, 2016

## GENERAL REQUIREMENTS

### R 333.5017 Records.

**Rule 17.** A registrant shall comply with all record requirements of these rules including, but not limited to, the use, storage, transfer, and disposal of each radiation machine.

History: 2016 MR 10, Eff. May 25, 2016

### R 333.5018 Inspections.

**Rule 18. (1)** Under the authority of MCL 333.13517(1), the department may enter at all reasonable times upon private or public property to conduct compliance investigations.

**(2)** Under the authority of MCL 333.13517(2), the department may obtain a warrant if necessary for search of property or seizure of sources of radiation or evidence of a violation of the act or any rule or license.

**(3)** A registrant shall make available to the department for inspection, all records maintained pursuant to these rules.

History: 2016 MR 10, Eff. May 25, 2016

### R 333.5019 Tests.

**Rule 19. (1)** A registrant shall make or cause to be made, tests that the department considers appropriate or necessary including, but not limited to, tests of the following:

- (a) The radiation machine.
- (b) Facilities where a radiation machine is used.
- (c) Radiation detection and monitoring instruments.
- (d) Other equipment and devices used in connection with the use of a radiation machine.

**(2)** The registrant shall allow the department to perform tests that it considers appropriate to determine compliance with these rules.

History: 2016 MR 10, Eff. May 25, 2016

### R 333.5020 Units of dose.

**Rule 20. (1)** As used in these rules, the units of dose are the following:

- (a) Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rads).
- (b) Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram. (0.01 Gy)
- (c) Sievert (Sv) is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor. (1 Sv = 100 rem)
- (d) Rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rads multiplied by the quality factor. (1 rem = 0.01 Sv)

**(2)** As used in these rules, the quality factors for converting absorbed dose to dose equivalent are shown in table 20-1:

**TABLE 20-1**

#### QUALITY FACTORS AND ABSORBED DOSE EQUIVALENCIES

Type of Radiation	Quality Factor*	Absorbed Dose Equal to a Unit Dose Equivalent
X, gamma, or beta radiation and high-speed electrons	1	1
Alpha particles, multiple-charged particles, fission fragments and heavy particles of unknown charge	20	0.05
Neutrons of unknown energy	10	0.1
High-energy protons	10	0.1

\*Absorbed dose in gray equal to 1 Sv or the absorbed dose in rad equal to 1 rem.

**(3)** If it is more convenient to measure the neutron fluence rate than to determine the neutron dose equivalent rate in sievert per hour or rem per hour, as provided in subrule (2) of this rule, 0.01 Sv (1 rem) of neutron radiation of unknown energies may, for purposes of these rules, be assumed to result from a total fluence of 25 million neutrons per square centimeter incident upon the body. If sufficient information exists to estimate the approximate energy distribution of the neutrons, the registrant may use the fluence rate per unit dose equivalent or the appropriate quality factor from table 20-2 to convert a measured tissue dose in gray or rad to dose equivalent in sievert or rem.

**TABLE 20-2**

**MEAN QUALITY FACTORS AND FLUENCE PER UNIT DOSE EQUIVALENT FOR MONOENERGETIC NEUTRONS**

Neutron Energy (MeV)	Quality Factor*	Fluence per Unit Dose Equivalent** (Neutrons cm <sup>-2</sup> Sv <sup>-1</sup> )	Fluence per Unit Dose Equivalent** (Neutrons cm <sup>-2</sup> rem <sup>-1</sup> )
(thermal)			
2.5 x 10 <sup>-8</sup>	2.0	9.8 x 10 <sup>10</sup>	9.8 x 10 <sup>8</sup>
1.0 x 10 <sup>-7</sup>	2.0	9.8 x 10 <sup>10</sup>	9.8 x 10 <sup>8</sup>
1.0 x 10 <sup>-6</sup>	2.0	8.1 x 10 <sup>10</sup>	8.1 x 10 <sup>8</sup>
1.0 x 10 <sup>-5</sup>	2.0	8.1 x 10 <sup>10</sup>	8.1 x 10 <sup>8</sup>
1.0 x 10 <sup>-4</sup>	2.0	8.4 x 10 <sup>10</sup>	8.4 x 10 <sup>8</sup>
1.0 x 10 <sup>-3</sup>	2.0	9.8 x 10 <sup>10</sup>	9.8 x 10 <sup>8</sup>
1.0 x 10 <sup>-2</sup>	2.5	1.0 x 10 <sup>11</sup>	1.0 x 10 <sup>9</sup>
1.0 x 10 <sup>-1</sup>	7.5	1.7 x 10 <sup>10</sup>	1.7 x 10 <sup>8</sup>
5.0 x 10 <sup>-1</sup>	11.0	3.9 x 10 <sup>9</sup>	3.9 x 10 <sup>7</sup>
1.0	11.0	2.7 x 10 <sup>9</sup>	2.7 x 10 <sup>7</sup>
2.5	9.0	2.9 x 10 <sup>9</sup>	2.9 x 10 <sup>7</sup>
5.0	8.0	2.3 x 10 <sup>9</sup>	2.3 x 10 <sup>7</sup>
7.0	7.0	2.4 x 10 <sup>9</sup>	2.4 x 10 <sup>7</sup>
1.0 x 10 <sup>1</sup>	6.5	2.4 x 10 <sup>9</sup>	2.4 x 10 <sup>7</sup>
1.4 x 10 <sup>1</sup>	7.5	1.7 x 10 <sup>9</sup>	1.7 x 10 <sup>7</sup>
2.0 x 10 <sup>1</sup>	8.0	1.6 x 10 <sup>9</sup>	1.6 x 10 <sup>7</sup>
4.0 x 10 <sup>1</sup>	7.0	1.4 x 10 <sup>9</sup>	1.4 x 10 <sup>7</sup>
6.0 x 10 <sup>1</sup>	5.5	1.6 x 10 <sup>9</sup>	1.6 x 10 <sup>7</sup>
1.0 x 10 <sup>2</sup>	4.0	2.0 x 10 <sup>9</sup>	2.0 x 10 <sup>7</sup>
2.0 x 10 <sup>2</sup>	3.5	1.9 x 10 <sup>9</sup>	1.9 x 10 <sup>7</sup>
3.0 x 10 <sup>2</sup>	3.5	1.6 x 10 <sup>9</sup>	1.6 x 10 <sup>7</sup>
4.0 x 10 <sup>2</sup>	3.5	1.4 x 10 <sup>9</sup>	1.4 x 10 <sup>7</sup>

\*Value of quality factor at the point where the dose equivalent is maximum in a 30-centimeter diameter cylinder tissue-equivalent phantom.

\*\*Monoenergetic neutrons incident normally on a 30-centimeter diameter cylinder tissue-equivalent phantom.

History: 2016 MR 10, Eff. May 25, 2016

**R 333.5021 Additional requirements.**

**Rule 21.** The department may impose additional requirements on a registrant in accordance with the act, 1978 PA 368, MCL 333.1011 to 333.25211, by rule, order, or registration conditions that it considers appropriate or necessary to minimize danger to public health and safety, property, and the environment.

History: 2016 MR 10, Eff. May 25, 2016

**ENFORCEMENT REQUIREMENTS**

**R 333.5023 Violations.**

**Rule 23. (1)** Under authority of MCL 333.13536, the department may obtain an injunction or other court order prohibiting a violation of the act, a rule, an order, or a registration condition issued under the act.

(2) Under the authority of MCL 333.2262, the department, in addition to taking other enforcement action, may impose a civil penalty, not to exceed \$1,000 for each violation, on a person who violates the act, a rule, an order, or a registration condition issued under the act. Each day that a violation continues shall constitute a separate violation.

(3) A person who violates the act, a rule, an order, or a registration condition issued under the act may be guilty of a misdemeanor and, on conviction, may be fined, imprisoned, or both, as provided by law.

History: 2016 MR 10, Eff. May 25, 2016

**R 333.5024 Emergency orders and impounding.**

**Rule 24. (1)** The department may issue an emergency order pursuant to MCL 333.13516. A person responsible for the radiation machine shall bear expenses incidental to the order.

(2) A radiation machine shall be subject to impoundment pursuant to MCL 333.13517. Impoundment by the department shall not relieve the owner of the responsibility for the radiation machine. A person who has a radiation machine impounded shall bear expenses incidental to the impoundment.

History: 2016 MR 10, Eff. May 25, 2016

**HEARING PROCEDURE**

**R 333.5026 Hearing procedure.**

**Rule 26. (1)** Before the issuance of an order, the department shall afford an opportunity for a hearing that shall be conducted pursuant to the administrative procedures act of 1969 PA 306, MCL 24.201 to MCL 24.328.

(2) In a contested case, the department shall conduct a hearing as provided in the administrative procedures act of 1969 PA 306, MCL 24.201 to MCL 24.328.

History: 2016 MR 10, Eff. May 25, 2016